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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/991,001	11/14/2001	Michael L. Bell	1840-045	4728
47626	7590	06/14/2005	EXAMINER	
SHELDON & MAK PC 225 SOUTH LAKE AVENUE 9TH FLOOR PASADENA, CA 91101			HAQ, SHAFIQU	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 06/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/991,001	<b>Applicant(s)</b> BELL ET AL.	
	<b>Examiner</b> Shafiqul Haq	<b>Art Unit</b> 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2-28 is/are pending in the application.  
     4a) Of the above claim(s) 4, 6, 8, 10, 13-21 and 24-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2, 3, 5, 7, 9, 11, 12, 22 and 23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/30/03, 7/22/02</u> | 6) <input type="checkbox"/> Other: ____  |

## **DETAILED ACTION**

### ***Status of Claims***

1. Applicants' responses and amendments filed on March 22, 2005 and April 27, 2005 to election requirement in Office Action mailed January 18, 2005 is acknowledged and entered.
2. Claim 1 is cancelled and new claims 22-28 are added.
3. Claims 4, 7-8, 10, 13-21 and 24-28 are withdrawn from further consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.
4. Claims 2, 3, 5-6, 9, 11-12 and 22-23 are examined on merits.

### ***Response to Election/Restriction***

5. Applicants' election with traverse of Group I filed on March 22, 2005 is acknowledged. Applicants erroneously included claim 13 in elected Group I (line 3, paragraph IV of response mailed in March 22, 2005) which is not considered and therefore, the elected Group I includes claims 2-12 and 22-23. Applicants' traversal is on the grounds that "a combined search and examination for restriction groups I-IV would not impose a serious burden". This is not found persuasive because of the reasons of record on pages 2-4 in Office Action of January 18, 2005. In addition, the search for each of the distinct inventions of Groups I-IV is not co-extensive particularly with regard to the literature search. Further, a reference that would

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anticipate the invention of one group would not necessarily anticipate or even make obvious another group.

Applicants remark (page 9 of March 22, 2005) that "alternative use suggested by the Office cannot be accomplished with Applicants claimed product" is not persuasive. Batch affinity process can be applied to purify antibody or antigen using the product of group I. The reagent comprising antigen or antibody sensor (i.e. antigen or antibody immobilized on insoluble particle) can be used to capture the corresponding antigen or antibody in a sample. After several wash cycles (centrifugation), the captured antigen and antibody can then be eluted by suspension in an appropriate buffer system and centrifugation to recover supernatant, which will contain captured antibody or antigen. Therefore, the inventions of group I and group II are distinct because the method of assaying or detection of an analyte (claims 13-17; group II) using the product of group I as claimed in claims 1-12 is materially different from the method of purification using the product of group I as suggested by the examiner.

The examiner respectfully disagrees with the Applicants for remarks on page 10 ("a combined examination of groups II and II does not impose a serious burden") because the condition for patentability is different in each case. A patentability determination for Invention I would require an assessment of the novelty and unobviousness of the reagent recited in claim 22 while a patentability determination for Invention II would require an assessment of the novelty and unobviousness of the method steps in claim 13. Furthermore, patentability determination for invention

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III would require an assessment of the novelty and unobviousness of the combination of kit components of claim 18 independent of any recited method of use. Thus, it will be an undue burden to examine all the inventive Groups in one application.

Applicants request to examine claims 24-28 with Group I is not considered because the newly submitted claims 24-28 are directed to method use (group II) that is distinct from the elected claims for the same reason of record on page 2 of last office action. Accordingly, Claims 24-28 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Finally, with respect to Applicants remarks on page 10 of response mailed in April 27, 2005, the examiner states the following:

Alkali metal (Li, Na, K, Rb, Cs, Fr) are patentably distinct from alkaline earth metal (Be, Mg, Ca, Sr, Ba, Ra) because they are different with respect to chemical and physical properties. Alkali metals are monovalent and are very reactive whereas alkaline earth metal are divalent and are less reactive.

Urea and Uric acid are structurally different and have different chemical properties (Urea is alkaline and Uric acid is acidic).

Fructose is structurally different from glucose and have different chemical and physical properties. Fructose is a ketose sugar and in its ring structure, fructose is recognized in having a five membered ring as compared to glucose which have a six membered ring. Therefore, the restriction requirement is still deemed proper and is made FINAL.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 9, 11-12 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
8. With respect to claim 23 it is not clear what is meant by the phrase "plurality of sample-insoluble particles". As for example, for ion-sensor particles (a), does the term "plurality of sample-insoluble particles" meant to include plural sensor particles associated with same target ionophores or different target ionophores? For antigen sensor, does the term meant to include plural sensor particles associated with same target antibody or different target antibody? Same applies to all other sensor particles.
9. Claims 9,11,12 are duplicates of claim 7 because enzyme-sensor particles (c) and nucleotide sensor particles (e) in claims 9, 11 and 12 are not considered as being non-elected species.

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 2, 3, 5-6, 9, 11-12 and 22-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Engh et al (US 5,747,349).

Claims recite reagents comprising different sensor particles for measuring target analytes in a sample.

Van den Engh et al. disclose reagents comprising different reporter beads (sensor particles: e.g. ion sensor particles, metabolite sensor particles) for assaying multiple analytes in a sample (see abstract). Van den Engh et al. disclose that ion sensor particles interact specifically with analyte selected from group consisting of alkali metal ions (column 3, line 8) and metabolite sensor particles interact specifically with analyte selected from group consisting of saccharide such as glucose (column 3, lines 10-11). The reference further disclose antigen-antibody coated fluorescent beads (antigen-antibody sensor particles) to detect corresponding antigen or antibody (column 1, lines 50-67) and disclose that beads tagged with different reporter molecules (sensor particles) can be mixed with one sample and plurality of analytes can be measured simultaneously (column 2, lines 40-42). The reference also disclose that specific interaction of reporter molecule (sensor particles) with the analyte leads to change in fluorescence properties of the reporter molecules (see lines 10-11 of the abstract; column 3, lines 66-67 and column 4, lines 1-13).

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As for claim 5, Van den Engh et al disclose wide range of bead sizes (<3  $\mu\text{m}$  to >10 $\mu\text{m}$ ) that can be utilized according to experimental needs (column 5, lines 19-31).

Therefore, the reference deems to anticipate the cited claims.

12. Claims 2, 3, 5-6, 9, 11-12 and 22-23 rejected under 35 U.S.C. 102(e) as being anticipated by McDevitt et al (US 6,680,206 B1).

McDevitt et al. disclose sensor arrays comprising plurality of sensitive particles (sensor particles) for identification of multiple analytes in a sample (see title and abstract and column 4, lines 35-49 and claims 2-3). The sensor particle may be of sizes ranging from 0.05 to 500 microns in diameter (column 8, lines 47-51) that encompass 0.1  $\mu\text{m}$  to 50  $\mu\text{m}$  of particles as claimed in claim 5 in present application. The particles may include various receptor molecules such as DNA (nucleic acid sensor), enzymes (enzyme sensors), antigens and antibodies (antigen-antibody sensor) to bind analyte of interest (column 5, lines 35-49; column 15, lines 63-67 and column 16, lines 1-12; column 20, lines 31-35, 54-57 and claims 20, 27-33) and to create a modulated signals (e.g. fluorescence) (column 15, lines column 18, lines 22-24, 66-67; column 19, lines 1-31 and claims 25, 26 and 36). The reagent also comprises ion sensor particles (e.g. for detection of pH, alkaline earth metal ions such as  $\text{Ca}^{+2}$ ) (column 17, lines 31-45; examples 1, 2 and claims 22-23) and metabolite sensor particles (e.g. for detection of saccharides) (column 6, lines 14-19 and claim 24) that interact with specific ions or metabolite to emit detected signals

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(e.g. fluorescence) (column 19, lines 9-31; column 24, lines 23-26, lines 56-61 and column 26, lines 17-23)

Therefore, the reference deems to anticipate the cited claim.

**Conclusion**

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shafiqul Haq whose telephone number is 571-272-6103. The examiner can normally be reached on 7:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SHAFIQU L HAQ  
EXAMINER  
ART UNIT 1641



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